II. REMARKS

This is filed in response to the final Office Action dated June 13, 2008, and accompanies a Request for Continued Examination and the required fees.

Applicants thank Examiner Leith for the courtesy extended to Applicants in the personal interview on August 5, 2008.

Claims 11-20 are pending.

By this amendment, claims 11, 14, and 16 are amended, new claims 21-24 are added, and claims 13, 18, and 19 are canceled. Applicants submit that support for the amendments can be found in the specification and claims as originally filed, for example, on Table 2 of the specification. Applicants submit that no new matter has been added and respectfully request reconsideration and withdrawal of the pending rejection.

Claims 11-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting over claims 59-66 of co-pending Application Serial No. 11/417,155 ("the '155 application") in view of Ammon et al. (European Patent No. EP 552657) in view of Balch et al. (Prescription for Nutritional Healing, 2nd Ed. Avery Publishing, Garden City Park, NY (1997) pp. 452-455) in view of Yegorova (U.S. Patent Appl. Pub. No. 2002/0176900). This rejection is respectfully traversed.

Presently amended independent claim 11 discloses "[a] method of treating psoriasis . . . comprising the steps of: a) orally administering . . . a composition comprising about 400 mg boswellic acid, about 100 micrograms of selenomethionine. . .three times per day ; and b) topically applying . . . a composition comprising 5% w/w

Boswellia serrata extract comprising boswellic acid... three times per day." Claims 12, 14-17 and 20 depend from independent claim 11. Claims 13, 18, and 19 have been canceled.

Applicants respectfully submit that none of the cited references, alone or in combination thereof, teach or suggest the unexpected results of the combination of an orally administered composition of boswellic acid and a selenium compound and topical application of a composition of boswellic acid, let the specific amounts claimed presently.

Applicants submit that the Declaration submitted with the previous Response filed on March 7, 2008, demonstrates these unexpected results. Applicants respectfully submit that this evidence of unexpected results of the claimed method is sufficient to overcome the *prima facie* case of obviousness asserted by the Examiner.

As admitted by the Examiner in the previous Office Action dated September 7, 2007, "[t]he claims of '155 do not specifically teach wherein the boswellic acid derivatives are combined with selenium compounds such as selenomethinione to be taken orally, while concurrently applying boswellic acid to the skin for treatment of psoriasis, nor the particular amount of boswellic acid derivatives or selenium compounds" and "Ammon et al. did not teach the incorporation of selenium such as selenomethionine for treatment of psoriasis nor the particular dosage amounts of boswellic acid derivatives and selenium compounds." Applicants respectfully submit that Balch et al. and Yegorova do not satisfy the deficiencies of the '155 application and/or Ammon et al., as they merely relate to selenium and do not teach or suggest the

combination of selenium and boswellic acid, much less the method of the present claims or the unexpected results thereof. In particular, Applicants submit that the cited references do not teach or suggest a method comprising the oral administration of "about 400 mg boswellic acid" and "about 100 micrograms of selenomethionine" and the topical administration of a composition comprising "5% w/w Boswellia serrata extract comprising boswellic acid," let alone their administration three times per day.

For at least the above reasons, Applicants respectfully request reconsideration and withdrawal of the provisional rejection of claims 11-20 on the ground of nonstatutory obviousness-type double patenting over claims 59-66 of the '155 application in view of Ammon et al., Balch et al., and Yegorova.

Claims 11-20 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ammon et al. (European Patent No. EP 552657) in view of Balch et al. (Prescription for Nutritional Healing, 2nd Ed. Avery Publishing, Garden City Park, NY (1997) pp. 452-455) in view of Yegorova (U.S. Patent Appl. Pub. No. 2002/0176900). This rejection is respectfully traversed.

Independent claim 11 and dependent claims 12, 14-17, and 20 have been discussed above. Claims 13, 18, and 19 have been canceled. As noted above, presently amended claim 11 is directed to a method comprising the steps of oral administration of "about 400 mg boswellic acid, about 100 micrograms of selenomethionine" and topical administration of a composition comprising "5% w/w Boswellia serrata extract comprising boswellic acid" three times per day.

Applicants further note that elemental selenium from different sources would have similar effects. Applicants submit the enclosed excerpt from The EFSA Journal (2008), 766, which states that selenium in selenium-enriched yeast produced using sodium selenite as a source is typically in the form of selenomethionine, accounting for approximately 60 to 85% of total selenium species in the selenium-enriched yeast product (p. 2-42).

As argued above, Applicants respectfully maintain that none of the cited references, alone or in combination thereof, teach or suggest the unexpected results of the combination of an orally administered composition of boswellic acid and a selenium compound and topical application of a composition of boswellic acid, in the specifically recited amounts, as in the presently claimed invention. Accordingly, for at least the above reasons, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 11-20 under 35 U.S.C. § 103(a) over Ammon et al., Balch et al., and Yegorova.

III. CONCLUSION

Applicants respectfully submit that this application is in condition for allowance and such action is earnestly solicited. If the Examiner believes that anything further is desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below to schedule a personal or telephone interview to discuss any remaining issues.

In the event this paper is not considered to be timely filed, Applicant hereby petitions for an appropriate extension of time. The fee for this extension may be charged to our Deposit Account No. 01-2300, referring to Attorney Docket No. **108064-00196**. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 01-2300, referencing Attorney Docket No. **108064-00196**.

Respectfully submitted,

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Enclosure: Excerpt from The EFSA Journal (2008): 766

efsa
European Food Safety Authority
The EFSA Journal (2008) 766, 1-42

Selenium-enriched yeast as source for selenium added for nutritional purposes in foods for particular nutritional uses and foods (including food supplements) for the general population [1]

Scientific Opinion of the Panel on Food Additives,

Flavourings, Processing Aids and Materials in Contact with Food

(Question No EFSA-Q-2005-078, EFSA-Q-2005-119, EFSA-Q-2005-186, EFSA-Q-2006-215, EFSA-Q-2006-216, EFSA-Q-2006-217)

Adopted on 9 July 2008

PANEL MEMBERS

F. Aguilar, H. Autrup, S. Barlow, L. Castle, R. Crebelli, W. Dekant, K.-H. Engel, N. Gontard, D. Gott, S. Grilli, R. Gürtler, J.-C. Larsen, C. Leclercq, J.-C. Leblanc, F. X. Malcata, W. Mennes, M.-R. Milana, I. Pratt, I. Rietjens, P. Tobback, F. Toldrá.

SUMMARY

Following a request from the Commission, the Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Foods (AFC Panel) was asked to deliver a scientific opinion on the safety and bioavailability of selenium-enriched yeast as a source for selenium when added for nutritional purposes in foods for particular nutritional uses and foods (including food supplements) for the general population.

The Scientific Committee for Food (SCF) has previously given an opinion on the Tolerable Upper Intake Level of selenium and has also provided an opinion on selenium in relation to the essential requirements for infant formulae and follow-on formulae.

The present opinion deals only with the safety and bioavailability of one particular source of selenium, selenium-enriched yeast, to be used in foods for particular nutritional uses and in foods (including food supplements) for the general population. The safety of selenium itself, in terms of amounts that may be consumed, is outside the remit of this Panel.

[1] For citation purposes: Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) on a request from the Commission on Selenium-enriched yeast as source for selenium. *The EFSA Journal* (2008) 766, 1-43.

Selenium in selenium-enriched yeast produced using sodium selenite as a source is typically in the form of the seleno-amino acid selenomethionine, accounting for approximately 60-85% of total selenium species in the selenium-enriched yeast product. Selenocysteine is the second most abundant identified species, approximating to 2-4% of total selenium species. Inorganic selenium (IV) ion is normally found at less than 1% of total, confirming that virtually all of the selenium present in the product is organically bound. The remaining proportion is the sum of minor species.

The conclusions of the present opinion relate only to selenium-enriched yeasts in compliance with the following product characteristics:

Selenium-enriched yeasts produced by culture in the presence of sodium selenite as selenium source and containing, in the dried form as marketed, not more than 2.5 mg selenium/g. The predominant organic selenium species present in the yeast is selenomethionine which constitutes between 60 and 85% of the total selenium in the product. The content of other organic selenium compounds including selenocysteine does not exceed 10%.

While levels of inorganic selenium in selenium-enriched yeast normally do not exceed 1%, since inorganic selenium in the form of sodium selenite, sodium selenate and sodium hydrogen selenite has been reviewed by the SCF and has been also permitted in PARNUTS and fortified foods, inorganic selenium from a selenium-enriched yeast source is not a safety issue.

Like other forms of selenium salts and organoselenium compounds, selenomethionine is readily absorbed from the gastrointestinal tract. In a number of studies in humans and animals, in particular those on selenium-deficient diets, the bioavailability of selenium from selenium-enriched yeasts and the bioavailability of selenomethionine has been shown to be approximately 1.5 to 2-fold higher than that of inorganic forms of selenium.

Following absorption, selenomethionine is metabolised to other functional forms of selenium (e.g. selenocysteine) or diverted into pathways of methionine metabolism and stored as selenoproteins. The half-life of L-selenomethionine (252 days) is longer than that of inorganic selenite (102 days), indicating that once absorbed, selenomethionine is incorporated into a long term body pool. The steady-state is reached after 6-12 months of supplementation with selenium in the form of selenomethionine or selenium-enriched yeast. The selenium is incorporated into tissue proteins such as skeletal muscle, liver, erythrocytes and plasma albumin from which it can subsequently be released by catabolism to maintain increased selenium status, indicating that selenomethionine is extensively utilized and re-utilized. Recent data in human volunteers show that in response to an increase in dietary selenium intake from sources such as selenium-enriched yeast, plasma selenium concentration increases to a new steady-state level that is maintained for many years if the level of selenium intake is unchanged.

Selenium is known to be chronically toxic and selenosis has been reported in humans and in food animals in seleniferous areas. Intakes in the range of 3200-6990 µg/day (mean 4990 µg/day) are associated with chronic selenosis, with no selenosis observed in the intake range of 240-1510 µg /day (mean 750 µg/day). Investigations into the health effects of high dietary intakes of selenium in populations living in the seleniferous areas of South Dakota, Venezuela and China have indicated that the highest long-term daily intake that can be ingested without the development of toxicity in most individuals is approximately 800 µg while prolonged intakes of daily selenium doses of 1000 µg or greater may cause adverse reactions.

Data in lactating women supplemented with selenium or exposed to high dietary selenium levels suggest that the mother acts as a buffer, protecting the infant against excess intake of selenium. Even at a maternal selenium intake of 300 µg/day (the recommended EC Tolerable Upper Intake Level) milk selenium concentration only rises to 60 µg/l giving an infant intake